3057. Misbranding of Ruko Aromatic Iodine Bath and Ruko Double Strength Pine Needle Bath. U. S. v. 12 Bottles, etc. (F. D. C. No. 28026. Sample Nos. 42932-K, 42933-K.)

LIBELS FILED: October 28, 1949, Northern District of Illinois; amended libels filed on November 8 and December 23, 1949.

ALLEGED SHIPMENT: Between the approximate dates of April 20, 1947, and September 23, 1949, by the Ruko Chemical Co., from Kew Gardens, N. Y.

PRODUCT: 12 1-pound bottles of *Ruko Aromatic Iodine Bath* and 17 1-pound bottles of *Ruko Double Strength Pine Needle Bath* at Chicago, Ill., together with a number of post cards entitled "Ruko Products."

Analysis disclosed that the *Ruko Aromatic Iodine Bath* consisted of a powder mixture containing sodium carbonate, sulfur, sodium sulfate, borax, and potassium iodide, scented with pine needle oil; and that the *Ruko Double Strength Pine Needle Bath* consisted of a powder mixture containing sodium carbonate, sodium sufate, borax, and pine needle oil.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the articles were false and misleading since the articles were not effective in the treatment of the conditions stated and implied: (Ruko Aromatic Iodine Bath) "Ind: In muscular and neuritic pains, high blood pressure and some cases of rheumatic arthritis. Reducing Treatments"; (Ruko Double Strength Pine Needle Bath) "Ind: General nervousness, insomnia, Graves' disease, anxiety, neurasthenia and heart neurosis" and "Soothing to the nerves."

DISPOSITION: April 13, 1950. Default decree of condemnation and destruction.

3058. Misbranding of Sinuothermic device. U. S. v. 16 Devices known as Sinuothermic and a number of leaflets. Tried to the court. Decree of condemnation and destruction. Judgment reversed upon appeal to court of appeals; judgment of court of appeals reversed by Supreme Court. (F. D. C. No. 17606. Sample No. 14003-H.)

LIBEL FILED: September 27, 1945, Southern District of Ohio; amended libel filed on or about October 2, 1945; second amended libel filed on or about January 9, 1947, in the Northern District of Florida, after removal of the case to that district for trial.

ALLEGED SHIPMENT: Between the approximate dates of June 1, 1945, and September 28, 1945, by Fred Urbuteit, from Tampa, Fla.

PRODUCT: 16 devices known as *Sinuothermic*, located at Cincinnati, Ohio, together with a number of leaflets entitled "The Road to Health."

The devices involved were of two externally different types, one of which was called the master unit and the other the treating unit. The master unit consisted of a wooden cabinet containing electrical parts, including three voltmeters, a milliamperemeter, a light switch, a potentiometer, a step-down transformer, and wires, and pad electrodes which were pieces of flat metal padded with wool felt on one side and sheet rubber on the other. The treating unit consisted of a wooden box containing the same electrical parts except for the voltmeters and milliamperemeter. The electrodes were intended to be applied to the area of the body in which pain existed, and the current was to be passed through the body by turning the potentiometer control to give a tingling sensation. The devices did not alter the form of the electrical current delivered from the ordinary wall socket to any other form of current, but merely stepped down the voltage to a maximum value of 60 volts.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the leaflets were false and misleading since they represented and suggested that the devices would be effective in the diagnosis, cure, mitigation, treatment, and prevention of painful breathing, internal growths, arthritis, hardening of the arteries, heart disease, paralysis, cancer, diabetes, tuberculosis, prostate trouble, deficient hearing, hay fever, infantile paralysis, glandular and nervous disorders, tumors of the bladder and uterus, uterine hemorrhage, diseased kidneys, nervousness, nerve disorders, peritonitis, low blood pressure, ulcerated colon, appendicitis, obstructed colon, and menstrual dysfunction, or discomfort associated with menstruation. The devices would not be effective for those purposes.

DISPOSITION: Fred Urbuteit, Tampa, Fla., and J. J. H. Kelsch, Cincinnati, Ohio, claimants, having denied that the devices were misbranded as charged in the libel, and the case having been removed to the Northern District of Florida on or about September 20, 1946, came on for trial before the court without a jury on January 23, 1947. The taking of testimony was concluded on January 24, 1947. On January 27, 1947, the court handed down the findings of fact and conclusions of law that the devices were misbranded within the meaning of the law and entered a decree condemning the devices and ordering their destruction.

A motion for a new trial filed by the claimant, Fred Urbuteit, was denied on February 6, 1947, and on April 21, 1947, upon motion of the Government, judgment taxing costs was entered against the claimants in the amount of $1,150.64. On May 1, 1947, a notice of appeal to the United States Court of Appeals for the Fifth Circuit was filed by Fred Urbuteit. The matter came on for argument before that court on October 22, 1947, and on November 7, 1947, the following opinion was handed down:

SIBLEY, *Circuit Judge:* "Under the Food, Drug and Cosmetic Act of 1938, Section 304 (21 U. S. C. A. § 334), sixteen electrical machines or devices were seized for condemnation in Ohio as having been misbranded when shipped in interstate commerce from Tampa, Florida, by appellant Fred Urbuteit to J. J. H. Kelsch at Cincinnati. The misbranding was alleged to consist of printed matter which accompanied them while in interstate commerce which was false and misleading in that it represented the machines as having therapeutic value in the diagnosis and treatment of stated diseases of man, whereas the devices were not effective for such purposes. Kelsch claimed six of them as his, and Urbuteit claimed ten of them as belonging to himself but rented to Kelsch. After trial, the case by consent having been transferred to Florida, a judgment of condemnation and destruction was rendered, with recovery of some $1,150.64 costs. Urbuteit appeals.

"The claims admit that six machines were sold by Urbuteit to Kelsch and shipped in interstate commerce as alleged and that the ten others were rented and shipped to Kelsch by express, and that the printed matter was at the request of Kelsch sent by Urbuteit to Kelsch by parcel post; but deny that it was a labeling of the machines or accompanied them, and deny that its statements are false and misleading. The testimony, in great volume, related mostly to the falsity of the statements. We consider first, however, whether there was a misbranding proven under the Act.

"Section 301 (a) (c) (21 U. S. C. A. § 331 (a) (c)) prohibits the introduction into and the receipt in interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded, and Section 304 (a) (21 U. S. C. A. § 334 (a)) provides for seizure and condemnation of such. It is not denied that these machines were devices within the Act. By Section 502 (a) (21 U. S. C. A. § 352 (a)) a drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular. A definition in Section 201 (21 U. S. C. A. § 321), which is the dictionary of the Act, is: '(m) The term labeling means all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' The last three quoted words are critical here. They make the

term 'labeling' broader than 'label' as defined in paragraph (k), which includes only what is 'displayed on the immediate container' of an article. How much broader? In *United States vs. Research Laboratories*, 126 F. (2) 42, it was held that printed matter which did not travel with the article but was sent by the same shipper to the same consignee and received at the same time for use in connection with the article, 'accompanied' it. But the same court in *Alberty vs. United States*, 159 Fed. (2) 278, refused so to hold when the printed matter and the article were shipped two months apart and not simultaneously. Accepting those decisions as sound, the latter controls here. It is shown that machines valued at $4,300 were shipped July 25, 1945; value $1,200 August 14; value $800 August 18; and value $1,200 Sept. 21. Kelsch testified that he had an understanding with Urbuteit that he would mail him some printed matter before he finally contracted for the machines, and that the matter was received about September, after the machines were delivered. It was found by the inspectors in Kelsch's consultation room, the machines being all in other rooms, on Sept. 5. The claim alleges the printed matter was mailed Sept. 1. It did not 'accompany' in any fair sense either shipment. Both the amended libel and the second amended libel allege that the false leaflets 'accompanied said articles of device when said articles were introduced into and while said articles of device were in interstate commerce.' This is the exact language of Section 304 (a), the forfeiture provision of the statute, but it is shown not to be true of any shipment. The first three shipments went forward and were received by Kelsch, and put to work in his medical practice several weeks before any leaflets were sent. They did not accompany any of the devices while they were in interstate commerce. The last shipment went forward three weeks behind the leaflets, and was not accompanied by them. Accompany means to go along with. In a criminal and forfeiture statute the meaning cannot be stretched.

"It may be doubted that the printed matter is in its nature a labeling for the machines. It looks like a small newspaper, entitled 'The Road to Health, By Dr. Fred Urbuteit. Every subject pertaining to Health, Doctoring and Nursing is being taught at the College of Sinuothermic Institute, Inc., 307 West Euclid Ave., Tampa, Florida.' To the left of this heading is a picture of Dr. Fred Urbuteit, President of Sinuothermic Institute, Inc., and to the right an attractive picture of the Institute and its grounds. Fifteen columns of fine print are below, consisting of testimonials and case histories of patients who had been treated at the Institute by Dr. Urbuteit, with unstinted praise of both. The Sinuothermic machine is mentioned and praised as an instrument of diagnosis and treatment, but there is no description or picture of the machine or any explanation of its operation, or any suggestion that it is for sale. The whole thing appears to be an advertisement for the Institute and Dr. Urbuteit, rather than something to accompany machines. Dr. Urbuteit is licensed as a practitioner of naturopathy in Florida. Dr. Kelsch is a chiropractor in Ohio. Dr. Kelsch became interested in Dr. Urbuteit's work and took a three weeks' course at the Institute, and on the strength of it, on returning to Ohio, bought some of the machines and rented others. He re-rented one to a patient to use at home, and sold one to another patient who moved to another State. The literature apparently was intended to advertise himself as following the methods of Dr. Urbuteit, rather than to explain or sell machines. Whether we ought to hold it a labeling of these machines if shipped simultaneously with them may be doubted. But if it could be called labeling, it is not proved by the present skimpy evidence that it accompanied the machines or any of them while they were in interstate commerce.

"Dr. Urbuteit vigorously contended that all he had said in 'The Road to Health' was true. He offered in his claim, since no employee of the United States had any actual knowledge of his machine and only a few practitioners whom he had instructed, to conduct a series of tests of it in cooperation with practitioners of medicine, osteopathy, chiropractic, and naturopathy approved by the court, on persons preferably before treated by medical practitioners without success, they to be examined before and after the test by physicians appointed by the court, during such period as the court should fix, their findings of the results to be evidence in the case. This was not done. Dr. Urbuteit at least seems convinced of the efficacy of his machine. He testifies that he was himself a suffering and distorted victim of arthritis deformans, and was helped to a degree which he described in detail, and exhibited his diseased joints to the court. He describes the contruction of his machine, claims peculiarities in the winding of the electrical transformers in it which experi-

mentally he found to produce currents peculiarly affected by diseased or congested bodily tissues, which when measured indicate where the trouble is, although often remote from the pain and other symptoms, and that it aided in locating the cause of trouble; and that a modified type of machine also was useful in treating many ailments. He testified in detail as to each case mentioned in 'The Road to Health.' He had thirty of his patients present whom he offered as witnesses to the benefits they had received, many of them being those mentioned in 'The Road to Health.' The judge refused to hear them, on the ground that being laymen they could not testify what was the matter with them and consequently could not say, what they were relieved from, and that the diagnoses testified to by Dr. Ubuteit could not be accepted because he rested them on the use of his machine which the Government's witnesses, who were men of high standing in medicine and in the electrical arts, had testified could not do what Dr. Urbuteit claimed. These rulings were error. One was based on the idea that Dr. Urbuteit had made his diagnoses solely on the indications of the machine. But his testimony as a whole was that he used all known methods of diagnosis, that the machine did not indicate any particular disease but only located the spot where the abnormal tissue was, and it was then a matter of judgment as to what the disease was. He only claimed the machine to be an aid in diagnosing. The patients themselves could certainly know whether their external symptoms abated and their pains ceased. Urbuteit, being a licensed doctor of some twenty years practice, could express expert opinions. The judge might, after hearing all the evidence, prefer the expert opinions of the Government witnesses to those of Dr. Urbuteit, even as against the facts to which he and his witnesses might swear, but he should have heard all the competent testimony before making up his mind. The most eminent physicians and scientists have in the past erred in their opinions, and opinions generally must yield to well proven contrary facts. The case ought to have been more fully tried.

"The judgment is reversed and the cause remanded for further proceedings consistent with this opinion."

A petition for a writ of certiorari was filed on behalf of the Government in the United States Supreme Court on February 6, 1948, and was granted on April 19, 1948. On November 22, 1948, after consideration of the briefs and arguments of counsel, the Supreme Court handed down the following opinion:

MR. JUSTICE DOUGLAS:

"The United States filed a libel under the Federal Food, Drug, and Cosmetic Act (52 Stat. 1044, 21 U. S. C. § 334), seeking seizure of 16 machines labeled 'Sinuothermic.' The libel alleged that the device was misbranded within the meaning of the Act (52 Stat. 1050, 21 U. S. C. § 352 (a)) in that representations in a leaflet entitled 'Road to Health' relative to the curative and therapeutic powers of the device in the diagnosis, cure, mitigation, treatment and prevention of disease were false and misleading. It charged that the leaflet had accompanied the device in interstate commerce.

"Respondent, Fred Urbuteit, appeared as claimant of several of the devices. He admitted that the devices and leaflets had been shipped in interstate commerce, but denied that they were shipped together or that they were related to each other. He also denied that the statements made in the leaflet were false or misleading. The case was tried without a jury and the articles were ordered condemned. The judgment was reversed by the Court of Appeals. 164 F. 2d 245. The case is here on certiorari to resolve the conflict between it and *Kordel* v. *United States*.

"Respondent Urbuteit terms himself a naturopathic physician and conducts the Sinuothermic Institute in Tampa, Florida. The machines against which the libel was filed are electrical devices allegedly aiding in the diagnosis and cure of various disease and physical disorders such as cancer, diabetes, tuberculosis, arthritis, and paralysis. The alleged cures effected through its use are described in the allegedly false and misleading leaflet, 'The Road to Health,' published by Urbuteit and distributed for use with the machines.

"Urbuteit shipped from Florida a number of these machines to one Kelsch, a former pupil of his who lives in Ohio. Kelsch used these machines in treating his patients and, though he did not receive them as a merchant, he sold some to patients. As part of this transaction Urbuteit contracted to furnish Kelsch with a supply of leaflets, which were sent from Florida to Ohio at a

different time than when the machines were forwarded. Kelsch used the leaflets to explain the machines to his patients.

"The leaflets seem to have followed the shipment of the machines. But as *Kordel* v. *United States* holds, that is immaterial where the advertising matter that was sent was designed to serve and did in fact serve the purposes of labeling. This machine bore only the words, 'U. S. Patent Sinuothermic Trade Mark.' It was the leaflets that explained the usefulness of the device in the diagnosis, treatment, and cure of various diseases. Measured by functional standards, as § 201 (m) (2) of the Act permits, these leaflets constituted one of the types of labeling which the Act condemns.

"The power to condemn is contained in § 304 (a) and is confined to articles 'adulterated or misbranded when introduced into or while in interstate commerce.'[1] We do not, however, read that provision as requiring the advertising matter to travel with the machine. The reasons of policy which argue against that in the case of criminal prosecutions under § 303 are equally forcible when we come to libels under § 304 (a). Moreover, the common sense of the matter is to view the interstate transaction in its entirety—the purpose of the advertising and its actual use. In this case it is plain to us that the movements of machines and leaflets in interstate commerce were a single interrelated activity, not separate or isolated ones. The Act is not concerned with the purification of the stream of commerce in the abstract. The problem is a practical one of consumer protection, not dialectics. The fact that the false literature leaves in a separate mail does not save the article from being misbranded. Where by funcional standards the two transactions are integrated, the requirements of § 304 (a) are satisfied, though the mailings or shipment are at different times.

"The Court of Appeals held that certain evidence tendered by Urbuteit as to the therapeutic or curative value of the machines had been erroneously excluded at the trial, a ruling that we are not inclined to disturb. Petitioner claims, however, that the error was not prejudicial. The argument is that since the evidence of the false and misleading character of the advertising as respects the diagnostic capabilities of the machines was overwhelming, that false representation was adequate to sustain the condemnation, though it be assumed that the therapeutic phase of the case was not established. We do not reach that question. Since the case must be remanded to the Court of Appeals, that question and any others that have survived will be open for consideration by it. *Reversed.*

"Mr. Justice Black, Mr. Justice Frankfurter, Mr. Justice Murphy, and Mr. Justice Jackson dissent for the reasons stated in their dissent in *Kordel* v. *United States*, No. 30, decided this day."

Upon remand of the case to the Court of Appeals for the Fifth Circuit, a motion was filed in that court on behalf of the Government to affirm the decree of condemnation of January 27, 1947, and on February 1, 1949, the court of appeals handed down the following decision:

SIBLEY, HUTCHESON, AND HOLMES, *Circuit Judges:* "Our judgment in this case, reported 164 Fed. (2) 245, was reversed in United States vs. Fred Urbuteit, . . . U. S. . . . , and the cause remanded to us for further proceedings in conformity with the opinion of the Supreme Court. The reversal was on the one point, that certain advertising matter shipped separately from any of the machines and held by us for that reason not to have 'accompanied' any of them might nevertheless constitute 'labeling,' if the movements of advertising and machines in interstate commerce were a single interrelated activity and not separate or isolated ones. There were four or five shipments of machines several weeks apart, and only one shipment of advertising. It does not appear whether there was a single interrelated activity in machines and advertising as to each shipment, or as to which shipments. That appears to be a question which should be further investigated.

"The Supreme Court did not disturb our former ruling that the district court should have heard all the evidence offered on the question of the falsity of the

[1] The relevant portion of this section reads as follows:
"Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce . . . shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdicion of which the article is found. . . ."

advertising. We adhere to that ruling. The judgment of the district court is accordingly reversed and the cause remanded for further proceedings in conformity with the opinion of the Supreme Court and with this opinion. *Judgment reversed.*"

Thereafter, the Government petitioned the Supreme Court for a writ of certiorari, and on May 2, 1949, the Supreme Court handed down the following decision:

"PER CURIAM: The question presented by this petition is whether the Court of Appeals followed our mandate on remand of the cause in 335 U. S. 355.

"The case when it was here earlier this Term appeared in the following posture:

"A condemnation proceeding was instituted by the United States under the Federal Food, Drug, and Cosmetic Act (52 Stat. 1044, 21 U. S. C. § 334). Sixteen machines with alleged diagnostic and curative capabilities had been shipped in interstate commerce. Leaflets describing the uses of the machine had been shipped at a separate time. The Court of Appeals had held that the separate shipments of the machines and leaflets precluded a conclusion that the leaflets had accompanied the device in interstate commerce, and therefore the transaction was outside the reach of the Act. We reversed the Court of Appeals and held that the separate shipment of the machines and leaflets constituted a single interrelated activity.

"On remand the Court of Appeals concluded that because there were several shipments of machines and a single shipment of advertising matter, it was not clear which shipments might be considered a single interrelated activity. Therefore, it remanded the case to the District Court for a determination of this fact.

"When the case was here before, we decided that the fact of separate shipments of machines and leaflets were immaterial. The controlling factors were whether the leaflets were designed for use with the machine and whether they were so used. Since the function of the leaflets and the purpose of their shipment were established, nothing more was needed to show that the movements of the machines and leaflets constituted a single interrelated activity. Moreover, the case is not complicated by shipments of machines and leaflets to different persons. One Kelsch was the recipient of both.

"On remand the Court of Appeals adhered to its former ruling that the District Court erroneously excluded evidence as to the therapeutic or curative value of the machines. When the case was here before we did not disturb that ruling. But we did leave to the Court of Appeals for consideration a further question—whether the evidence as respects the falsity of the diagnostic capabilities of the machine was adequate to sustain the condemnation even though error in exclusion of the other evidence were conceded. The United States is entitled to a hearing on that question.

"The petition for certiorari is granted and the judgment is *Reversed.*"

Following the remanding of the case to the Court of Appeals for the Fifth Circuit, the Government renewed its motion that the decree of condemnation of January 27, 1947, be affirmed. This motion was granted on August 2, 1949, Circuit Judge Sibley dissenting with the following opinion:

SIBLEY, *Circuit Judge:* "My brethren feel compelled by the opinions of the Supreme Court in this case to grant the Government's motion to affirm the decree of the District Court forfeiting the sixteen electric machines seized as misbranded. The last mandate does not direct us to affirm. If it did, the full responsibility for a wrong decision would be on the Supreme Court. It remands the case to us for further proceedings in conformity with the opinions of the Supreme Court, and this remand requires us to exercise a judicial and not a ministerial function. To join in the affirmance would make me feel both foolish, and false to my judicial oath to support the Constitution of the United States which I think is being violated. This bold statement needs to be justified.

"The second amended libel describes the machines as 'numbered X8 and X10 of the so-called Master Type, the others bearing numbers T20, T23, (naming 14), of the so-called Treating Unit Type.' Dr. Kelsch filed a claim to the machines X8, X10, T20, T25, T26, and T32. Dr. Fred Urbuteit disclaimed any interest in these six, having sold them to Dr. Kelsch, but he filed a claim to the remaining ten T-type machines which he alleged he had rented to Dr. Kelsch. The evidence is clear that the ownership was as stated. It is also clear that the

Master Type machines alone have voltmeters and milliampere meters and dials for reading them, and that this type alone is used by the practitioner in diagnosing. The Treating Type machines are for use by patients and have nothing to do with diagnosing. Assuming the falsity of statements in the 'Road to Health' as to capacity to diagnose, these statements relate only to the diagnosing machines. The false statements as to successful treatment relate only to the Treating Type. The difference is like that between X-ray machines which take photographs for diagnosis and those which apply such rays to the patient in treatments. The district judge, in paragraph 3 of his findings of fact, distinguishes the two types of machine and their use; and in paragraph 5 he deals with the Master Type machines and their use in diagnosing, and concludes: 'The Master Machine therefore is incapable of diagnosing any diseased condition.' In paragraph 6 he turns to the question of therapeutic and curative effects and finds, on the incomplete evidence before him, that no such effect is or can be produced. He therefore condemned all the machines.

"Dr. Kelsch did not appeal his case. His 6 machines stand condemned, including both the X8 and X10 Master Type Machines. Urbuteit appealed, and his ten Treating Type rented machines alone are now before this court. No one has ever represented that the treating type machines were useful in diagnosing. The evidence as to usefulness in treatment has not been fully heard, thirty witnesses for Urbuteit being present and ready to testify, but excluded for a reason this court has held to be insufficient. It must be assumed, on this motion to affirm for false statements as to diagnosis only, that these ten machines are useful for treatment, the purpose for which they are intended. It therefore seems to me foolish to say that because Urbuteit sold two Master Type Machines to Kelsch which were mislabeled as to diagnostic powers, he forfeited also ten machines of another kind which he later rented and shipped to him.

"The skimpy but uncontradicted evidence as to the printed leaflets, 'The Road to Health,' is that before buying his first machines Dr. Kelsch asked Dr. Urbuteit to send him some copies, and some were sent by mail about September 1, 1945, and mailed out by Dr. Kelsch to some of his patients. Machines had been shipped July 25, August 14, and August 18, 1945. The last three were shipped September 21, 1945. It does not appear whether these shipments were on separate orders. The Supreme Court, without evidence or a finding by the district judge, has said they were a 'single interrelated activity' with the sending of the printed leaflets. I suppose that we are to understand that all reorders of foods, drugs, cosmetics and devices are forfeited if the first lot be falsely labelled. This would be in keeping with the holding that these leaflets 'accompanied' any of these machines. They did not. The forfeiture of these devices, good or bad, would be impossible except for the Federal Food, Drug and Cosmetics Act, 21 U. S. C. A. Section 334, providing for forfeiting of 'Any . . . device that is misbranded . . . while in interstate commerce.' Misbranding includes false labeling. Section 321 (m) declares 'The term "labelling" means all labels and other written, printed or graphic matter (1) *upon* any article or any of its containers or wrappers, or (2) *accompanying* such article.' [*Emphasis added.*] The printed matter here is said to have accompanied these machines 'while in interstate commerce' because it was mailed to the same person several weeks after some of the machines were sent and several weeks before others. The only interstate commerce in which the machines ever were was their transportation from Florida to Ohio, in four separate express shipments. No machine was in interstate commerce except during its transportation. All but three had arrived and been delivered in Ohio from two weeks to six weeks before any printed matter was started. How could they be thereby 'misbranded' while in interstate commerce?

" 'Accompany' is a plain English word wholly unambiguous. It was used by Congress to *define*, not *to be defined*. It defines not only a *forfeiture* but also a *crime*. What it means in forfeiting property it also means in forfeiting liberty in a criminal prosecution under the statute. All the dictionaries I have seen say it means 'to go along with.' They say also it is used in music, but who would think a pianist 'accompanies' a soloist, if he performs an hour before or after? I surely do not 'accompany' another on any trip if I either precede or follow by a space of weeks. The courts here are adding words to the definition made by Congress, and making it read 'accompany, or precede or follow in an inter-related activity.' And an 'interrelated activity' is badly in need of definition itself. To thus amend a plain statute is to legislate, and for the

courts to do it is to violate the very first sentence in our Constitution: 'All legislative powers herein granted shall be vested in the Congress of the United States which shall consist of a Senate and House of Representatives.' The courts have no right to alter a statutory definition; or otherwise try to make a tighter law than Congress has made. Sworn to uphold the Constitution, judges ought to be careful about engaging in judicial legislation. I can accomplish nothing here, but I feel bound to protest. I am not concerned so much about Dr. Urbuteit and his machines, which may be worthless or worse, but I am greatly concerned about unlawful perversion of the statutory law."

A petition for rehearing filed by the claimant, Fred Urbuteit, was denied on September 13, 1949, and the petition of this claimant to the Supreme Court for a writ of certiorari was denied on February 6, 1950. On April 21, 1950, upon motion of the Government, an order was entered by the United States District Court for the Northern District of Florida, directing that in lieu of destruction four of the devices be delivered to the Food and Drug Administration.

3059. Misbranding of Drown Radio Therapeutic Instrument. U. S. v. 1 Device, etc. (F. D. C. No. 28009. Sample No. 60624–K.)

LIBEL FILED: October 4, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: The device and certain printed matter were transported by Edgar Rice on or about October 28, 1948, from Los Angeles, Calif., to Blue Island, Ill., and certain printed matter was shipped from Los Angeles, Calif., by the Drown Laboratories in May or June 1948, and on March 10 and April 28, 1949.

PRODUCT: 1 *Drown Radio Therapeutic Instrument* at Blue Island, Ill., together with a leaflet entitled "Drown Atlas," circulars entitled "The Drown Radio Diagnostic Therapeutic Photographic Instruments," and a diagnostic chart entitled "The Drown Radio Therapy."

Examination showed that the device was a closed box resembling a radio set, equipped with 15 dials, 3 terminal posts, and an ammeter or voltmeter.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the leaflets, circulars, and diagnostic chart were false and misleading since the device was not effective for the purposes or conditions stated or implied. The statements represented and suggested that the device was effective in forming healthy cells, measuring functions of the body, making blood counts and urinalyses, determining blood pressure, determining temperature, and diagnosing and treating diseases and abnormalties in any part of the body, including, but not limited to, kidney and bladder complications, adhesions, tipped uterus, extra kidneys, painful urination, paralysis, inability to talk, heart trouble, noises in the ear, constipation, pains in lower back, effects of scarlet fever, septicemia in left mastoid, headache, streptococcus, abscesses, loss of speech and memory, inability to digest food, vomiting bile, diseases of the glands, female organs, male organs, and blood, and colds and sore throat.

DISPOSITION: November 11, 1949. Default decree of condemnation. The court ordered that the device and the printed matter be released to the Food and Drug Administration.